UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

11/16/2017

SUBJECT: Acute Toxicity Review for Durisan UP-RTU, EPA Reg. No.: 88919-R

FROM: Ian Blackwell, M.S., Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny Tao, Team Leader (Acute Toxicology)
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff, PM Team 31/Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Sanit Technologies, LLC		
Decision No.: 530885	Submission No.: 1005463	E-Sub No.: none
DP No.: 441694	Action Code: A540	
MRID No(s).: 50318105 - 50318110		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
069149	7173-51-5	1-Decaminium, N-decyl—N,N-dimethyl-, chloride	1.6
		Other Ingredients	98.4
		Total	100.0%

I) BACKGROUND

The Registrant, Sanit Technologies, LLC, has submitted an application for pesticide registration for their product: *Durisan UP-RTP,* EPA Reg. No. 88919-R, *Durisan UP-RTP* is a disinfectant, cleaner, and deodorizer. For this submission, they have presented a complete set of six acute toxicity and irritation studies (a "six-pack") to satisfy their data requirements.

II) FINDINGS/RECOMMENDATIONS

1) Each of the submitted six studies is acceptable to support the registration of the proposed product.

2) The acute toxicity profile of *Durisan UP-RTP,* EPA Reg. No. 88919-R, is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	50318105	IV	Acceptable
Acute Dermal Toxicity	50318106	IV	Acceptable
Acute Inhalation Toxicity	50318107	III	Acceptable
Primary Eye Irritation	50318108	III	Acceptable
Primary Skin Irritation	50318109	II	Acceptable
Dermal Sensitization	50318110	sensitizer	Acceptable

III) PRODUCT LABELING

1) The Signal Word: WARNING

2) The statement, "Keep Out of Reach of Children (KOROC)", is required. It should appear immediately below the front-panel signal word "WARNING".

3) The Agency's Label Review Manual (https://www.epa.gov/pesticide-registration/label-review-manual) indicates the following human-hazard precautionary statements:
PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

WARNING. Causes skin irritation and moderate eye irritation. Harmful if inhaled. Avoid breathing (dust, vapor or spray mist). Do not get on skin or clothes. Avoid contact with eyes. Avoid breathing (dust, vapor or spray mist). Wear coveralls worn over short-sleeved shirt and short pants, socks, waterproof or chemical-resistant gloves and chemical-resistant footwear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

4) **FIRST AID:**

If on skin:

– Take off contaminated clothing.
– Rinse skin immediately with plenty of water for 15-20 minutes.
– Call a poison control center or doctor for treatment advice.

If in eyes:

– Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
– Call a poison control center or doctor for treatment advice.

If inhaled:

– Move person to fresh air.
– If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
– Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 50318105 **Study Completion Date**: 1/26/2017
Lab Study No.: 44441

Testing Laboratory: Product Safety Labs
Authors: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Durisan UP-RTU; "Clear liquid"

Species: Sprague-Dawley albino rat
Weight: 179-205 g **Age**: 10-11 weeks
Source: SAGE Labs

Conclusion:

1. LD_{50} (mg/kg): **Males=** Not tested
Females> 5,000 mg/kg
Combined= Not tested

2. The estimated LD_{50} is greater than 5,000 mg/kg of body weight.

3. Tox. Category: IV **Classification**: Acceptable

Procedure (Deviations from 870.1100): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	Not tested	0/3	---

Observations: Reduced fecal volume, active and healthy.

Gross Necropsy: No gross abnormalities.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 50318106 **Study Completion Date**: 1/20/2017
Lab Study No.: 44442

Testing Laboratory: Product Safety Laboratories
Author: Jennifer Durando, B.S.
Quality Assurance (40 CFR §160.12): Included

Test Material: Durisan UP-RTU; "Clear liquid", Lot #: 062316

Species: Sprague-Dawley-derived albino rat
Weight: Males= 296-328 g **Age**: 9 weeks
Females= 172-196 g
Source: SAGE Labs

Summary:

- **Summary**:
- **1. LD_{50} (mg/kg)**:
-
-
-
-
- **2. The estimated LD_{50} is greater than 5,000 mg/kg of body weight.**
-
- **3. Tox. Category**: IV **Classification**: Acceptable
-

Males= > 5,000 mg/kg
Females= > 5,000 mg/kg
Combined= > 5,000 mg/kg

Procedure (Deviation from 870.1200): One animal had dose pad dislocated at approximately 5 hours prior to the 24-hour unwrapping time (at roughly 19-hour post dosing). The dose pad was immediately rewrapped when found for the remaining 5-hour exposing time.

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000 mg/kg	1/5	0/5	1/10

Observations: One male died within one day of post-dosing; no adverse clinical signs observed prior to death. Blanching, erythema, edema, eschar, "hyper sensitive", hyperkeratosis, desquamation, sloughing of skin, and discoloration were noted in all surviving animals between Day 1 and 14.

Gross Necropsy Findings: Lungs and liver discolored in the deceased male animal. No abnormalities were noted during necropsy in the surviving animals.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (870.1300)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 50318107 **Study Completion Date**: 6/16/2017
Lab Study No.: 44443

Testing Laboratory: Product Safety Laboratories
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Durisan UP-RTU; "Clear liquid
Concentration: nose-only chamber
1. gravimetric= 2.09 mg/L; nominal= 47.34 mg/L,
2. gravimetric= 0.54 mg/L; nominal= 20.13 mg/L analytical
3. gravimetric= 0.61 mg/L; nominal= 3.64 mg/L

Species: Sprague-Dawley derived albino rat
Weight: Males= 257-270 g Females= 180-210 g
Age: 8-9 weeks
Source: SAGE Labs

Summary:

1. **LC_{50} (mg/L)** **Males=** $0.61 < X < 2.09$ mg/L
Females= $0.61 < X < 2.09$ mg/L
Combined= $0.61 < X < 2.09$ mg/L
2. **The estimated LC_{50} is between 0.61 and 2.09 mg/L of air.**
3. **MMAD:** (See Table) **µm**
4. **Toxicity Category:** III **Classification:** Acceptable

Procedure (Deviation from 870.1300): The lab first tested the gravimetric concentration of 2.09 mg/L (nominal chamber concentration of 47.34 mg/L) resulted in a 90% mortality rate (5/5 males and 4/5 females died). Later the testing of the 0.54 mg/L gravimetric concentration (nominal chamber concentration of 20.13 mg/L) of test material led to a mortality rate of 10/10. The lab retested, per the registrant's request, at 0.61 mg/L

analytical concentration (nominal chamber concentration of 3.64 mg/L). The study report was based on the results of the analytical concentration of 0.61 mg/L.

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.09 mg/L (gravimetric)	5/5	4/5	9/10
0.54 mg/L (gravimetric)	5/5	5/5	10/10
0.61 mg/L (analytical)	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < 4.7 μm
2.09	2.08 μm	2.15 μm	83.9 μm
0.54	1.82 μm	2.02 μm	93.6 μm
0.61	2.43 μm	2.22 μm	78.2 μm

Chamber Environment			
Chamber Volume	28 liters (nose-only)		
Concentration (mg/L)	0.61	0.54	2.09
Airflow (LPM)	36-40	36.0	36.0
Temperature (° C)	26-28	17-19	18-19
Relative Humidity	26-28%	57-63%	62-70%

Clinical Observations:

At 0.61 mg/L (analytical): All animals survived although all exhibited abnormal respiration. One male was hypoactive and another male exhibited ano-genital staining. All animals

recovered by Day 6 and appeared active and healthy for the remainder of 14-day observation period.

At 0.54 and 2.0 mg/L (gravimetric): Irregular respiration, gasping, moist rales, Hypoactivity, ano-genital staining, prone, cold to touch, death.

Gross Necropsy Findings:

At 0.61 mg/L (analytical): No gross abnormalities were observed.

At 0.54 mg/L and 2.0 mg/L (gravimetric): Lungs discolored, stomach and intestines distended.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400)

Product Manager: 31
MRID No.: 50318108

Reviewer: I. Blackwell
Study Completion Date: 1/26/2017
Lab Study No.: 44444

Testing Laboratory: Product Safety Labs
Author(s): Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Durisan UP-RTU; "clear liquid"
Dosage: 0.1 mL

Species: New Zealand white rabbit
Weight: 2176-2568 g
Source: Robinson Services

Sex: Female
Age: 11 weeks

Summary:

1. **Toxicity Category**: III

2. **Classification**: Acceptable

Procedure (Deviations from 870.2400): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	10	14
Corneal Opacity	0/3	2/3	2/3	1/3	1/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3	0/3	0/3	0/3	0/3
Conjunctivae								
Redness	0/3	1/3	2/3	1/3	0/3	0/3	0/3	0/3
Chemosis	3/3	3/3	2/3	1/3	1/3	0/3	0/3	0/3
Discharge	3/3	0/3	0/3	0/3	0/3	0/3	0/3	0/3

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (870.2500)

Product Manager: 31
MRID No.: 50318109

Reviewer: I. Blackwell
Study Completion Date: 1/19/2017
Lab Study No.: 44445

Testing Laboratory: Product Safety Labs
Author: Jennifer Durando, BS

Quality Assurance (40 CFR §160.12): Included

Test Material: Durisan UP-RTU; "clear liquid"
Dosage: 0.5 mL

Species: New Zealand albino rabbit
Weight: 2582-2628 g
Age: 12 weeks
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category**: II

2. **Classification**: Acceptable

Procedure (Deviations from 870.2500): None

Results: One hour after treatment with the test material, 1/3 animals had well-defined erythema, 2/3 had very slight erythema and 3/3 had moderate erythema. Twenty-four hours after treatment, 3/3 very slight erythema, 2/3 slight edema and 1/3 moderate edema. Forty-eight hours after treatment, 1/3 had severe erythema, 2/3 well-defined erythema, 2/3 slight edema, 1/3 very slight edema and blanching in 1/3. Seventy-two hours (Day 3) after, 1/3 had moderate-to-severe erythema, 2/3 well-defined erythema, 1/3 slight edema and 2/3 very slight edema. On Day 7, 2/3 females had very slight erythema. No more erythema or edema was observed after the 7th day. On the 10th and 14th days, the lab reported fissuring and desquamation.

Special Comments: The lab ended the study after day 14 due to a lack of irritation.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (870.2600)

Product Manager: 31
MRID No.: 5031810

Reviewer: I. Blackwell
Study Completion Date: 1/26/2017
Lab Study No.: 44446

Testing Laboratory: Product Safety Labs
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Durisan UP-RTU, "clear liquid"
Positive Control Material: α-HexylCinnamAldehyde (HCA)

Species: Mouse, CBA/J
Weight: 17.8 – 21.5 g
Age: 9 weeks
Source: Envigo RMS, Inc.

Method: Local Lymph Node Assay (LLNA)

Summary:

1. **This Product is a dermal sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviation from 870.2600): None

Results:

Local Lymph Node Assay				
Animal Group	Test Substance Concentration	Average Count per Mouse	Number of Mice in Group	Test/ Vehicle Control Ratio
Vehicle Control	100%	2683.37	5	---
Positive Control	25%	17315.14	5	6.45
Test Substance	100%	27835.87	5	10.37